



INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 1149WOORD01	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/EP2004/050493	International filing date (day/month/year) 08/04/2004	(Earliest) Priority Date (day/month/year) 11/04/2003
Applicant ALTANA PHARMA AG		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box II).

3. ☐ Unity of invention is lacking (see Box III).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

ORAL PHARMACEUTICAL PREPARATION COMPRISING A PROTON PUMP ANTAGONIST AND A BASIC EXCIPIENT

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

10/ 551 943

Claims Nos.: 1-26 partly

Present independent claim 1 relates to an extremely large number of possible oral dosage forms, namely all those comprising: 1) a reversible PPI ("proton pump antagonist" or APA), and 2) a basic excipient, with no restriction or limitation, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such dosage forms, namely film-coated immediate release tablets comprising soraprazan (as defined in claim 18) and a basic compound as defined in claims 15 and 16. Other possibilities are not sufficiently disclosed in the application. In particular, it is not proved that the stabilising effect is also achieved for other APAs different from soraprazan. The area covered by the claims is broader than justified by the extent of the disclosure. It follows that the claims so lack support, and/or the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. It is the same for independent claims 22 and 23.

Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the dosage form by reference to the result to be achieved, expressed in terms of parameters (disintegration rate; see claims 3, 6-10 and 23-25), which only amounts to claiming the technical problem to be solved instead of claiming the relevant technical features which amount to its solution. This lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to claim 1 taken in combination with claims 5, 15 and 16, and 18, as interpreted in connection with the description and the examples.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

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International application No.
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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 1-26 partly
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/20 A61K31/4439 A61K9/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/45693 A (BYK GULDEN LOMBERG CHEM FAB ; LINDER RUDOLF (DE); NEY HARTMUT (DE); DI) 13 June 2002 (2002-06-13) cited in the application page 44, line 9 - page 46, line 6 examples 27-29 page 40, paragraph 5 page 41, paragraph 2 page 42, paragraph 3 example N -----	1-26
X Y	DE 199 25 710 A (BYK GULDEN LOMBERG CHEM FAB) 14 December 2000 (2000-12-14) column 3, line 40 - line 63 column 4, line 23 - line 28 column 4, line 60 - line 68 examples column 5, line 18 - line 25 ----- -/--	1-16, 22-26 17-21

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

2 December 2004

Date of mailing of the international search report

10/12/2004

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/74654 A (BYK GULDEN LOMBERG CHEM FAB ; LINDER RUDOLF (DE); DIETRICH RANGO (DE)) 14 December 2000 (2000-12-14)	1-16, 22-26
Y	page 6, paragraph 6 - page 7, paragraph 4 examples	17-21
X	----- US 2002/045646 A1 (PHILLIPS JEFFREY O) 18 April 2002 (2002-04-18)	1-16, 22-26
Y	paragraphs '0036!', '0037!', '0085! - '0090!', '0278!', '0394!', '0398! - '0403!', '0418! - '0432!', '0436! - '0446! Tablet D3, example I table 8	17-21
P,X	----- US 2004/028737 A1 (DESHMUKH SATISH RAMACHANDRA ET AL) 12 February 2004 (2004-02-12)	1-16, 22-26
	examples 3,4	
X	----- EP 1 222 922 A (EISAI CO LTD) 17 July 2002 (2002-07-17)	1-16, 22-26
Y	examples 4-8; table 2	17-21
X	----- US 6 299 904 B1 (SHIMIZU TOSHIHIRO ET AL) 9 October 2001 (2001-10-09)	1-16, 22-26
Y	column 6, line 65 - column 7, line 34 example 5	17-21
X	----- US 4 786 505 A (ODA MINORU ET AL) 22 November 1988 (1988-11-22)	1-16, 22-26
Y	examples 9,10	17-21
X	----- WO 98/50019 A (CHEN JIVN REN ; SAGE PHARMACEUTICALS INC (US)) 12 November 1998 (1998-11-12)	1-16, 22-26
Y	examples	17-21
X	----- WO 00/78284 A (LAHAV RAFFAEL ; AZOULAY VALERIE (IL); DEXCEL LTD (IL)) 28 December 2000 (2000-12-28)	1-16, 22-26
Y	examples 1,4,10,13	17-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/050493

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